



4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2016-N-2474]**

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0605. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species--

21 CFR Part 516

OMB Control Number 0910-0605--Extension

The Minor Use and Minor Species (MUMS) Act (Pub. L. 108-282) amended the Federal Food, Drug, and Cosmetic Act to authorize FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are "MUMS-designated" by FDA. Minor use drugs are drugs for use in major species (e.g., cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species (e.g., zoo animals, ornamental fish, parrots, ferrets, and guinea pigs). Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees. Participation in the MUMS program is completely optional for drug sponsors, so the associated reporting only applies to those sponsors who request and are subsequently granted "MUMS designation."

Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees. Section 516.20 provides requirements on the content and format of a request for MUMS-drug

designation; § 516.26 provides requirements for amending MUMS-drug designation; § 516.27 provides for change in sponsorship of MUMS-drug designation; § 516.29 provides for termination of MUMS-drug designation; § 516.30 contains the requirements for annual reports from sponsor(s) of MUMS-designated drugs; and § 516.36 sets forth consequences for insufficient quantities of MUMS-designated drugs.

*Description of Respondents:* The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

In the *Federal Register* of June 12, 2019 (84 FR 27333), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1--Estimated Annual Reporting<sup>1</sup>

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
516.20; content and format of MUMS request	15	5	75	16	1,200
516.26; requirements for amending MUMS designation	3	1	3	2	6
516.27; change in sponsorship	1	1	1	1	1
516.29; termination of MUMS designation	2	1	2	1	2
516.30; requirements of annual reports	15	5	75	2	150
516.36; insufficient quantities	1	1	1	3	3
Total					1,362

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community, and has not changed since the last OMB approval.

Dated: December 2, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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